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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,909	11/04/2003	John R. Erbey II	CV06093	7785

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,909	ERBEY ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *25-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :22 April 2004, 30 April 2004, 7 May 2004, 27 September 2004, and 21 January 2005.

DETAILED ACTION

Status of the Claims

1. Claims 1-3 and 11-26 are pending in the application, with claims 25-26 having been withdrawn from consideration, in response to the restriction requirement submitted on November 2, 2006. Claims 4-10 have been cancelled according to a Preliminary Amendment filed on March 21, 2005. Accordingly, claims 1-3 and 11-24 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group I, namely claims 1-3 and 11-24, in the reply filed on November 28, 2006 is acknowledged. The traversal is on the ground(s) that the search for the system of Group I would uncover the method of Group II. This is not found persuasive because many products can be used with the process of Group II and thus the search for the products of Group I will not necessarily yield the process of Group II. Furthermore, if the product claims of Group I are found allowable, then the process claims of Group II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai.*

Claims 28-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on November 28, 2006.

Additionally, Applicant's election with traverse of the species of a compound of formula II (ezetimibe) and of an autoimmune disorder (Multiple Sclerosis), in the reply filed on November 28, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on April 22, 2004, April 30, 2004, May 7, 2004, September 27, 2004, and January 21, 2005 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 and 11-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an autoimmune disorder, does not reasonably provide enablement for preventing an autoimmune disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex*

parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to (1) a method of preventing an autoimmune disorder comprising administering a sterol absorption inhibitor of Formula (I), (2) a method of preventing an autoimmune disorder comprising administering a sterol absorption inhibitor of Formula (II), and (3) a method for preventing rheumatoid arthritis comprising administering a sterol absorption inhibitor of Formula (I).

(2). ***State of the Prior Art***:

The skilled artisan would view that the prevention of a disorder, e.g. an autoimmune disorder such as rheumatoid arthritis or multiple sclerosis, is highly unlikely.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of autoimmune disorders is extremely high.

(4). ***Predictability of the Art***:

The prevention of a disorder such as an autoimmune disorder is highly unpredictable. It

is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the administration of a sterol absorption inhibitor of Formula (I) or Formula (II) as a preventive for any autoimmune disorder.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the method for preventing autoimmune disorders comprising administrating a sterol absorption inhibitor of the instant invention is limited.

The disclosure of the methods of manufacturing a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 48-51, example 1). The disclosure of the method for treating experimental arthritis comprising administrating a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 51-52, expample 2). The disclosure of the method for treating uclerative colitis comprising administrating a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 52-53, expample 3).

(7). ***Working Examples***:

The working examples in the specification show how to manufacture a sterol absorption inhibitor of Formula (II) (pages 48-51, example 1), how to evaluate the ability of a sterol absorption inhibitor of Formula (II) to treat experimental arthritis using an animal model of rheumatoid arthritis (collagen-induced arthritis in DBA/1 or B10.RIII mice) (pages 51-52, example 2), and how to evaluate the ability of a sterol absorption inhibitor of Formula (II) to treat ulcerative colitis using a animal model of colitis (2,4,6-trinitrobenzene sulfonic acid-induced colitis in mice) (pages 52-53, example 3). Thus, the working examples show how to manufacture a sterol absorption inhibitor of Formula (II) and treat with a sterol absorption inhibitor of Formula (II), not how to prevent.

Note that lack of a working example to prevent, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of a preventive agent represented by Formula (I) or Formula (II). As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

4. Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating arthritis and ulcerative colitis, does not reasonably provide enablement for treating any autoimmune disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to (1) a method of treating an autoimmune disorder comprising administering a sterol absorption inhibitor of Formula (I) and (2) a method of treating an autoimmune disorder comprising administering a sterol absorption inhibitor of Formula (II).

(2). ***State of the Prior Art***:

The skilled artisan would view that the treatment of a vast array of any autoimmune disorders, is highly unlikely.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of autoimmune disorders is extremely high.

(4). ***Predictability of the Art***:

The treatment of a vast array of autoimmune disorders with a sterol absortion inhibitor of Formula (I) or Formula (II) is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the administration of a sterol absorption inhibitor of Formula (I) or Formula (II) as a treatment for any autoimmune disorder.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the method for treatment of any autoimmune disorders comprising administrating a sterol absorption inhibitor of the instant

invention is limited.

The disclosure of the methods of manufacturing a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 48-51, example 1). The disclosure of the method for treating experimental arthritis comprising administrating a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 51-52, expample 2). The disclosure of the method for treating uclerative colitis comprising administrating a sterol absorption inhibitor of Formula (II) of the instant invention is adequate (pages 52-53, expample 3).

(7). ***Working Examples***:

The working examples in the specification show how to manufacture a sterol absorption inhibitor of Formula (II) (pages 48-51, example 1), how to evaluate the ability of a sterol absorption inhibitor of Formula (II) to treat experimental arthritis using an animal model of rheumatoid arthritis (collagen-induced arthritis in DBA/1 or B10.RIII mice) (pages 51-52, example 2), and how to evaluate the ability of a sterol absorption inhibitor of Formula (II) to treat ulcerative colitis using a animal model of colitis (2,4,6-trinitrobenzene sulfonic acid-induced colitis in mice) (pages 52-53, example 3). Thus, the working examples show how to manufacture a sterol absorption inhibitor of Formula (II) and treat rheumatoid arthritis and ulcerative colitis with a sterol absorption inhibitor of Formula (II), not how to treat any autoimmune disorder.

Note that lack of a working example to treat any autoimmune disorder, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of an agent represented by Formula (I) or Formula (II) to treat any autoimmune disorder. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

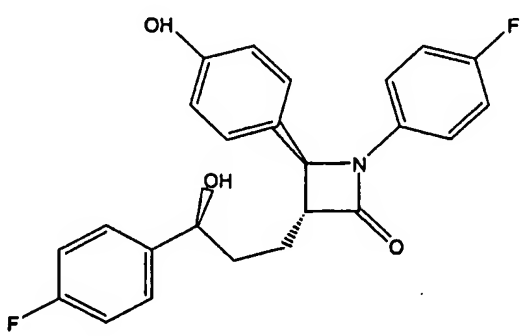
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, 2nd paragraph for having insufficient antecedent basis from the independent claim, claim 1.

Claim 3 recites the limitation of "at least one sterol absorption inhibitor is represented by Formula (II):



",

which lacks sufficient antecedent basis from claim 1. The sterol absorption inhibitor of Formula (II) is not recited in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 12-17, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (6,569,879).

Liu et al. teach a method for treating inflammatory conditions, including rheumatoid arthritis and multiple sclerosis by administering a sterol absorption inhibitor, ezetimibe (column 11, lines 34 and 49-50).

Liu et al. also teach peroxisome proliferators activated receptor (PPAR) agonists that are useful for the treatment of an autoimmune disorder (column 11, line 25).

Furthermore, Liu et al. teach HMG-CoA reductase inhibitors such as atorvastatin and simvastatin (column 11, lines 28-29).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 11 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (6,569,879) as applied to claims 1-3, 12-17, and 20-24 above, in view of Vaccaro et al. (5,656,624) and Somers (6,147,250).

Liu et al. do not teach the administration of a sterol absorption inhibitor in an amount ranging from about 0.1 to about 1000 mg per day.

Liu et al. also do not teach sterol absorption inhibitors that disrupt lipid raft formation of leukocytes.

Vaccaro et al. teach administering azetidinone derivatives in an amount ranging from about 0.1 to about 30 mg per day (column 13, lines 55-56).

Somers teaches HMG-CoA reductase inhibitors to lower low density lipoprotein, LDL, levels as well as new compounds that inhibit the expression of vascular cell adhesion molecule-1, VCAM-1 (column 5, lines 10-14 and column 7, lines 12-14).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the sterol absorption inhibitor of Liu et al. in the amount ranging form about 0.1 to about 1000 mg per day to disrupt the cell membrane organization of leukocytes and affect adhesion molecule function because the compounds of Vaccaro et al. and Somers are sterol absorption inhibitors and HMG-CoA reductase inhibitors and according to Vaccaro et al. and Somers, sterol

absorption inhibitors and HMG-CoA reductase inhibitors in an amount ranging from about 0.1 to 1000 mg per day inhibit adhesion molecule function in leukocytes.

The motivation to combine the compounds of Liu et al. to the compounds of Vaccaro et al. and Somers is that the compounds of Vaccaro et al. and Somers are sterol absorption inhibitors and HMG-CoA reductase inhibitors and that such terol absorption inhibitors and HMG-CoA reductase inhibitors inhibit adhesion molecule function in leukocytes.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-3, 11, 17-21, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 16, 27, and 29-32 of Davis et al. (7,053,080) and claims 1-3,17, 19-20, 23-27, 29-30, and 32 of Davis et al. (7,071,181).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 16, 27, and 29-32 of Davis et al. (7,053,080) and claims 1-3,17, 19-20, 23-27, 29-30, and 32 of Davis et al. (7,071,181) are directed at a sterol absorption inhibitor of Formula (I) or Formula (II), which is the same sterol absorption inhibitor of Formula (I) or Formula (II) used in a method for treating an autoimmune disorder in the instant claims 1-3, 11, 17-21, and 24. Thus the sterol absorption inhibitor of Formula (I) or Formula (II) is not patentably distinct between Davis et al. (7,053,080), Davis et al. (7,071,181), and the instant application.

9. Claims 1-3, 11, 17-21, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 35-37, 44, and 47 of copending Application Kosoglou et al. (U.S. Patent Application No. 2002/0147184), claims 1-2, 34-38, 46, and 49 of copending Application Kosoglou et al. (U.S. Patent Application No. 2003/0069221), claims 19-20 of copending Application Fine et al. (U.S. Patent Application No. 2004/0092500), claims 1-3, 16, 27, and 29-32 of copending Application Davis et al. (U.S. Patent Application No. 2006/0009399), and claims 1-15 and 21-25 of copending Application Veltri (U.S. Patent Application No. 2006/0069080). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 35-37, 44, and 47 of Kosoglou et al. (U.S. Patent Application No. 2002/0147184), claims 1-2, 34-38, 46, and 49 of Kosoglou et al. (U.S. Patent Application No. 2003/0069221), claims 19-20 of Fine et al., claims 1-3, 16, 27, and 29-32 of Davis et al., and claims 1-15 and 21-25 of Veltri are directed at a sterol absorption inhibitor of Formula (I) or Formula (II), which is the same sterol absorption inhibitor of Formula (I) or Formula (II) used in a method for treating an autoimmune disorder in the

instant claims 1-3, 11, 17-21, and 24. Thus the sterol absorption inhibitor of Formula (I) or Formula (II) is not patentably distinct between Kosoglou et al. (U.S. Patent Application No. 2002/0147184), Kosoglou et al. (U.S. Patent Application No. 2003/0069221), Fine et al., Davis et al., Veltri, and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

10. Claims 1-3, 11, 17-21, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 33-35 of Davis et al. (7,053,080) and claims 21-22, 28, 31, and 33-34 of Davis et al. (7,071,181) in view of Liu et al. (6,569,879), Vaccaro et al. (5,656,624), and Somers (6,147,250) as applied to claims 1-24 above and in further view of Davis et al (7,053,080), Davis et al. (7,071,181), and Fine et al. (U.S Patent Application No. 2004/0092500).

Davis et al (7,053,080) teach a method of treating obesity comprising administering a sterol absorption inhibitor of Formula (II) (column 2, lines 37-41). Davis et al. (7,071,181) teach a method to treat diabetes comprising administering a sterol absorption inhibitor of Formula (II) (column 3, lines 43-47). Davis et al. (7,071,181) also teaches that there is an increased rate of cardiovascular and peripheral vascular diseases in patents with diabetes (column 2, lines 3-5). Fine et al. teach a method for treating demyelination comprising administering a sterol absorption inhibitor of Formula (II) (page 1, paragraph [0011]).

11. Claims 1-3, 11, 17-21, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 10, and 13-18 of copending Application Fine et al. (U.S. Patent Application No. 2004/0092500), claims 28 and

33-35 of copending Application Davis et al. (U.S. Patent Application No. 2006/0009399), and claims 16-20 and 31-39 of copending Application Veltri (U.S. Patent Application No. 2006/0069080) in view of Liu et al. (6,569,879), Vaccaro et al. (5,656,624), and Somers (6,147,250) as applied to claims 1-24 above and in further view of Davis et al (7,053,080), Davis et al. (7,071,181), and Fine et al. (U.S Patent Application No. 2004/0092500).

Davis et al (7,053,080) teach a method of treating obesity comprising administering a sterol absorption inhibitor of Formula (II) (column 2, lines 37-41). Davis et al. (7,071,181) teach a method to treat diabetes comprising administering a sterol absorption inhibitor of Formula (II) (column 3, lines 43-47). Davis et al. (7,071,181) also teaches that there is an increased rate of cardiovascular and peripheral vascular diseases in patents with diabetes (column 2, lines 3-5). Fine et al. teach a method for treating demyelination comprising administering a sterol absorption inhibitor of Formula (II) (page 1, paragraph [0011]).

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER